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510K Summary
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K022069

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date:	June 21, 2002
Name of Submitter:	GE OEC Medical Systems 384 Wright Brothers Drive Salt Lake City, UT 84116 801-874-778
Corresponding Official:	Bill Gislason Vice President, Quality Assurance, Regulatory and Reliability
Device Proprietary Name:	OEC® FluoroTrak™ 9800 Plus
Classification Name:	Image Intensified Fluoroscopic X-ray System with Image Processing System
Common/Usual Names:	Fluoroscopic Imaging System with Interactive Image Guided Surgical System
Substantial Equivalence:	The OEC FluoroTrak 9800 Plus is substantially equivalent to the OEC 9800 Mobile Digital Imaging System (K974355) marketed by GE OEC Medical Systems, Inc. and the InstaTrak 3000 System with FluoroTrak Module (K994270) marketed by Visualization Technology, Inc.

Indications for Use

The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.

General Description

The OEC FluoroTrak 9800 Plus is the result of mechanically integrating the Instatrak 3000 System with FluoroTrak Module (marketed by Visualization Technology, Inc.) into the workstation of the OEC 9800 Mobile Imaging System.

The 9800 Mobile Imaging System is an image intensified fluoroscopic system consisting of a mobile C-arm and OEC Workstation. The C-arm supports the high-voltage generator, x-ray tube, x-ray controls, and image intensifier. The C-arm is designed to perform linear and rotational motions that allow the user to position the x-ray imaging components at various angles and distances with respect to the patient. The OEC workstation is a mobile platform that supports image display monitors, image processing and recording devices.

The InstaTrak 3000 System is an image guidance system indicated for use during sinus, skull base, cranial and axial skeletal procedures. Using the InstaTrak 3000, the surgeon can readily identify the immediate location and position of the surgical instrument during the indicated procedure.

The InstaTrak 3000 System allows the surgeon to view reconstructed two-dimensional images of the patient's anatomy in response to an electromagnetically tracked surgical instrument. This indicates the position of the tracked surgical instrument with regard to the patient's anatomy based on pre-operative medical images.

The InstaTrak 3000 System with FluoroTrak Module (K994270) is being mechanically integrated into the workstation of the OEC 9800 Mobile Imaging System (K974355) to form the system configuration marketed as the OEC FluoroTrak 9800 Plus. The intended use of both the InstaTrak 3000 System with FluoroTrak Module and the OEC 9800 Mobile Imaging System remains the same as described in their respective original 510(k)s.

Product Standards

The OEC FluoroTrak 9800 Plus is designed in accordance with product safety and performance requirements established in the following standards:

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
ANSI/NFPA 70 & 99	National Electrical Code and Standard for Health Care Facilities
UL 2601	Medical Electrical Equipment
CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment
IEC 60601-1	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment, Electromagnetic Compatibility
IEC 60601-1-3	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray
IEC 60601-1-4	Medical Electrical Equipment, Programmable Electrical Medical Systems
IEC 60601-2-7	Medical Electrical Equipment, HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment, X-ray Tube and Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment, Safety of Associated X-ray Equipment
93/42/EEC - Annex 1	Essential Requirements of the Medical Devices Directive

This concludes this 510(k) Summary.

GE OEC MEDICAL SYSTEMS, INC.

Bill Gislason

Bill Gislason
Vice President, Quality Assurance, Regulatory, and Reliability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

Mr. Bill Gislason
Vice President, Quality Assurance,
Regulatory and Reliability
GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
SAKT LAKE CITY UT 84116-2862

Re: K022069
Trade/Device Name: OEC FluoroTrak 9800 Plus
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 JAA and IZL
Dated: June 21, 2002
Received: June 25, 2002

Dear Mr. Gislason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Applicant: GE OEC Medical Systems, Inc.

510(k) No. (if known): K022069

Device name: OEC FluoroTrak 9800 Plus

Indications for use: The OEC FluoroTrak 9800 Plus Mobile Imaging System provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The Fluorotrak surgical navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022069

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)